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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,507	05/29/2002	Dorra Cherif	52.US2.PCT	9446

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EXAMINER

HORLICK, KENNETH R

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/807,507

Applicant(s)

CHERIF, DORRA

Examiner

Kenneth R. Horlick

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1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11,27-32 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11,27-32 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/13/05:5/29/02</u> . | 6) <input type="checkbox"/> Other: _____  |

1. Reference M on the IDS filed 05/29/02, Dutrillaux et al., has been lined through as not considered because it is not in English.
2. Applicant's election without traverse of Group I, claims 11, 27-32, and 37, in the reply filed on 01/13/05 is acknowledged.
3. Claims 33-36 and 38-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/13/05.
4. Claims 11 and 27-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - A) These claims are confusing because "the Alu and LINE DNA sequences" and "the Alu DNA sequences" in independent claims 11 and 27 lack proper antecedent basis. Correction is required.

B) Claims 27-32 are further confusing because it cannot be determined what is encompassed by IRS-PCR amplification "with the aid of primers specific for the Alu and LINE DNA sequences". Clarification is required as to exactly what primer(s) are contemplated and how they are to be used in the method.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Wilgenbus et al. (1995).

This claim is drawn to a method comprising: mixing first and second amplification products obtained from two IRS-PCR amplification reactions from chromosomes, wherein the first amplification products are obtained using Alu- and LINE-specific primers and the second amplification products are obtained using Alu-specific primers.

Wilgenbus et al. teach such a method (see especially pages 215-216). Near the bottom of page 215 it is recited that with respect to YAC-containing whole yeast DNA, "PCR reactions were carried out in two separate reactions, using only one Alu-primer (directed either towards the 5' or the 3' Alu-consensus sequence) with or without the LINE1 primer". This is shown in the left side of the flow chart in Figure 1 on page 216. As the cited teaching specifically notes that the LINE1 primer may or may not be

present, the case where it is present in one of the two reactions but not in the other reads on the claimed method.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Speicher et al. in view of Siciliano et al. (US 5,538,869).

This claim is drawn to a kit comprising at least a combination of a specific fluorophore, a specific absorption or excitation optical filter, and a specific emission optical filter, selected from the specific seven listed combinations.

Speicher et al. teach a combination of the fluorophore Cy7, the excitation filter Omega 740DF25, and the emission filter Omega 780EFLP (see Table 1 on page 369). This corresponds to the embodiment set forth in alternative "(e)" of claim 37.

Speicher et al. do not teach a kit.

One of ordinary skill in the art would have been motivated to make a kit comprising the noted fluorophore, excitation filter, and emission filter of Speicher et al. because it was conventional in the art at the time of the invention to package together reagents into a kit for the convenience of practicing methods requiring said reagents. For example, Siciliano et al. recite kits in claims 18-20. It would have been prima facie

obvious to one of ordinary skill in the art at the time of the invention to make the claimed kit in order to practice the method of Speicher et al.

7. Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Lichter et al., Lengauer et al., or Wilgenbus et al., in view of Speicher et al.

These claims are drawn to methods comprising: performing multicolor FISH analysis using probes obtained by IRS-PCR amplification "with the aid of" primers specific for Alu and LINE DNA sequence.

Each of the primary references teaches using probes obtained by IRS-PCR amplification using primers specific for Alu and LINE DNA sequence in FISH analysis (see especially pages 6635-6637 in Lichter et al.; pages 2-5 in Lengauer et al.; and pages 215-220 in Wigenbus et al.).

None of the primary references teaches multicolor FISH analysis.

Speicher et al. teach karyotyping human chromosomes by multicolor FISH analysis (see entire reference on pages 368-375). These teachings cover one of the specific fluorophore/absorption filter/emission filter combinations of claim 28 as described above (see Table 1 on page 369). Regarding claim 32, the abstract on page 368 teaches detection of chromosome rearrangements.

One of ordinary skill in the art would have been motivated to apply the IRS-PCR probes generated using Alu and LINE primers, as taught by any one of the primary references, in multicolor FISH analysis, because Speicher et al. taught the numerous applications and benefits of multicolor FISH analysis. It would have been prima facie

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obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,562,959. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim and the instant claim are related essentially as species-genus.

9. Claim 37 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 6,562,959. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim and the instant claim are related essentially as species-genus.

10. Claims 11 and 27-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28 and 30-37 of copending Application No. 10/251,699. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims and the instant claims are related essentially as species-genus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. No claims are free of the prior art.

12. Garini et al. (US 6,066,459), Bittner et al. (US 5,776,688), and Ward et al. (US 6,060,251) are made of record as references of interest.

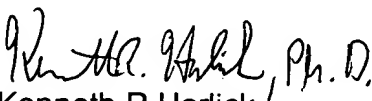
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kenneth R Horlick  
Primary Examiner  
Art Unit 1637

03/31/05